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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-----------------|-------------|----------------------|-------------------------|------------------|
| 10/082,579      | 02/25/2002  | Lukas Eisermann      | 4002-2949               | 5700             |
| 7590            | 10/24/2003  |                      |                         |                  |
|                 |             |                      | EXAMINER                |                  |
|                 |             |                      | RAMANA, ANURADHA        |                  |
|                 |             |                      | ART UNIT                | PAPER NUMBER     |
|                 |             |                      | 3732                    |                  |
|                 |             |                      | DATE MAILED: 10/24/2003 |                  |
|                 |             |                      | 9                       |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/082,579             | EISERMANN ET AL.    |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Anu Ramana             | 3732                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on July 16, 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-23 and 32-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12, 14-23, 42, 44-46, 49-53 and 56-57 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 13,32-41,43,47,48,54 and 55 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Species II (Figures 5(a), 5(b), 6, 7 and 8) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that claims readable on Species I, II, III and IV can be readily examined together. This is not found persuasive because contrary to Applicants' opinion, searching for different species is burdensome and is not reasonable.

Consequently, the requirement is still deemed proper and is therefore made FINAL.

It is acknowledged that claims 1 and 51 are generic to Species I, II, III and IV. Accordingly, claims 1-12, 14-23, 42, 44, 45, 46, 49, 50, 51, 52, 53 and 57 readable on elected Species II have been examined. Claims 13, 32-40, 41, 43, 54 and 55 are withdrawn from consideration as they read on a nonelected species. Cancellation of claims 24-31 is noted. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

The use of trademarks "DACRON" (page 3, line 12), "GORE-TEX" (page 3, line 12), "OSTEOFIL" (page 11, line 9), "SONGER" (page 15, line 1) and "PARALLAX" (page 16, line 14) has been noted in this application. Trademarks should be capitalized wherever they appear and should be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter of claims 49 and 50. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-7, 12, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wall (4,502,161).

Regarding claims 1, 3-7, 12, 22 and 23, Wall discloses an orthopedic implant or plate 10 made of a woven fine fabric mesh of stainless steel with a reinforcing band or strut 12 (Figures 1, 5 and 6, col. 1, lines 9-12, col. 3, lines 23-30 and lines 53-62 and col. 4, lines 12-14).

Claims 1-8, 10-12 and 15-20 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalnberz et al. (US 4,089,071).

Regarding claims 1-8, 10-12 and 15-23, Kalnberz et al. disclose a bone endoprosthesis or implant with a chemically inert metal net or mesh 1, made of titanium or its alloys, and a biologically inert elastic polymeric material net or mesh 2 wherein mesh 1 overlays mesh 2 and is secured to mesh 2 with one or more reinforcing elements or polymer threads and wherein a curable polymer such as epoxy resin containing a pharmaceutical agent or antiseptic is provided for embedding the overlying meshes 1 and 2 (col. 1, lines 6-11, col. 4, lines 46-68, col. 5, lines 1-6, col. 7, lines 45-68, col. 8, lines 1-21).

Claims 42, 44, 45, 50-53, 56 and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Henderson et al. (US 6,066,175).

Regarding claims 42, 44, 45, 50-53, 56 and 57, Henderson et al. disclose an orthopedic implant made of metallic mesh or a “plurality of metallic fibers” bounded by a reinforcing band with two locking screws or “elongate members or rods” or “reinforcing members” 11 extending across the mesh wherein the implant contains an osteogenic polymer or material (Figures 1, 3, 4, 8 col. 1, lines 13-19, col. 5, lines 53-57, col. 6, lines 32-52 and col. 7, lines 6-21). The elongate members 11 inherently have a tensile strength greater than a selected fiber of the metallic mesh.

The method steps of claims 45 and 50 are inherently performed during normal use of the Henderson et al. implant for the purpose of bone fusion.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 14, 42, 44, 45, 46, 49, 50-53, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wall in view of Frey et al. (US 4,955,911).

Regarding claims 2, 14, 42, 44, 45, 46, 49, 50-53, 56 and 57, Wall discloses an orthopedic implant or plate 10 made of a woven fine fabric mesh of stainless steel with a reinforcing band or strut 12 and two elongate members 28 extending across a portion of the network (Figures 1, 5 and 6, col. 1, lines 9-12, col. 3, lines 23-30 and lines 53-62 and col. 4, lines 12-14). The elongate members 28 inherently have a tensile strength greater than a fiber of the metallic mesh.

Wall does not disclose an osteogenic material adhered to a portion of the implant to promote bone growth.

Frey et al. teach a bone implant made of a wire fabric wherein the implant can be coated with a substance promoting the invasion of tissue or “an osteogenic material” (col. 3, lines 6-11).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the Wall implant with an osteogenic material as taught by Frey et al., to promote bone growth.

The method steps of claims 45, 46, 49 and 50 are performed during normal use of the implant of the combination of Wall and Frey et al. for the purpose of treating a bone defect.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalnberz et al. in view of Mulhauser et al. (US 6,267,772).

Kalbernz et al. do not disclose a second set of fibers or mesh made of a biodegradable material. See discussion for claim 8.

Mulhauser et al. teach an absorbable mesh made of biodegradable polyglycolic acid for applications involving temporary repair (col. 4, lines 45-48).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a second mesh in the Kalbernz et al. implant, made of a biodegradable material, taught by Mulhauser et al., for applications involving temporary repair.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalbernz et al.

Kalbernz et al. disclose that the reinforcing element can be made of polymer. See discussion for claim 1.

Although Kalbernz et al. do not disclose that the reinforcing element can be made of a shape memory polymeric or metallic alloy material, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the reinforcing element of shape memory polymeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 3732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anuadhe Ramana*  
October 20, 2003

*Pedro Philogene*  
PEDRO PHILOGENE  
PRIMARY EXAMINER